

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
1 July 2004 (01.07.2004)

PCT

(10) International Publication Number  
**WO 2004/054645 A2**

(51) International Patent Classification<sup>7</sup>: **A61M 5/32, 5/20**

NJ 08648 (US). **HABESHAW, Rosemary, Louise**  
[GB/GB]; 84A Blinco Grove, Cambridge CB1 7TS (GB).

(21) International Application Number:  
PCT/GB2003/005494

(74) **Agents: TUNSTALL, Christopher, Stephen** et al.; Carp-  
maels & Ransford, 43-45 Bloomsbury Square, London  
WC1A 2RA (GB).

(22) International Filing Date:  
17 December 2003 (17.12.2003)

(81) **Designated States (national):** AF, AG, AI., AM, AT, AU,  
AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR,  
CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD,  
GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,  
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN,  
MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU,  
SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,  
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(25) Filing Language: English

(26) Publication Language: English

(30) **Priority Data:**  
0229404.9 17 December 2002 (17.12.2002) GB  
0325596.5 3 November 2003 (03.11.2003) GB

(84) **Designated States (regional):** ARIPO patent (BW, GH,  
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,  
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE,  
SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,  
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) **Applicant (for all designated States except US): CILAG**  
**AG INTERNATIONAL** [CH/CH]; Landis & Gyrstrasse  
1, CH-6300 Zug (CH).

(72) **Inventors; and**

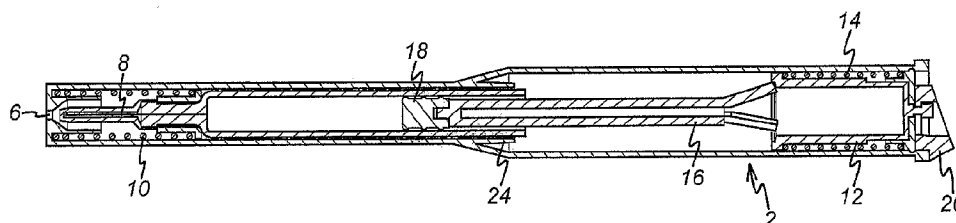
(75) **Inventors/Applicants (for US only): HARRISON, Nigel,**  
**David** [GB/GB]; 15 Barley Way, Linton, Cambridge  
CB1 6YN (GB). **BRADY, Matthew, James** [GB/GB];  
6 Wattle Close, Cambourne, Cambridgeshire CB3 6BU  
(GB). **BERMAN, Gregory** [GB/GB]; 45 Highfield Ave-  
nue, Cambridge CB4 2AJ (GB). **JOHNSTON, David,**  
**Maxwell** [GB/US]; 12134 East Run Drive, Lawrenceville,

**Published:**

— *without international search report and to be republished  
upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

(54) **Title:** INJECTION DEVICE



(57) **Abstract:** An injection device including a housing for containing a syringe having a bore extending from an end surface, a needle communicating with the bore through the end surface and a dispensing piston movable in said bore towards said end surface so as to expel the contents of the syringe through the needle, the housing having an opening at one end through which the needle may extend, a resilient member for biasing the syringe and the needle inwardly off the housing, a first coupling element moveable towards said one end so as to move the needle of the syringe out of the opening and to move the dispensing piston of the syringe towards the end surface, a mechanism operable to release the syringe such that the needle moves inwardly off the housing, a drive coupling for extending from said first coupling element to the dispensing piston of the syringe so as to transfer movement of said first coupling element to the dispensing piston wherein the mechanism is triggered to release the syringe and includes components to delay release of the syringe until a predetermined period after being triggered such that it can be ensured that the dispensing piston reaches the end surface before the syringe is released and/or the mechanism includes an inertial mass moveable with the first coupling element and drive coupling and a release member actuable by the inertial mass to release the syringe such that when the dispensing piston releases the end surface of the syringe and the first coupling element and drive coupling stop moving, the inertial mass continues to move so as to actuate the release member to release the syringe.



WO 2004/054645 A2

### Injection Device

The present invention relates to an injection device, in particular an injection device which, having dispensed the contents of a syringe, automatically retracts the needle of the syringe.

5

Devices exist which are spring loaded to extend automatically the needle of a syringe from the device, dispense the contents of the syringe and then automatically retract the needle. WO 95/35126 describes such a device.

- 10 As illustrated in Figure 1 of the accompanying drawings, the device includes a housing 2 in which a syringe 4 is contained. The housing 2 includes an opening 6 through which the needle 8 of the syringe 4 may extend. A retraction spring 10 biases the syringe 4 away from the opening 6. The device also includes a drive element 12 which is biased by a spring 14 to drive a coupling 16 to move the dispensing piston 18 of the syringe 4. In use, a
- 15 release mechanism 20 releases the drive element 12 such that the syringe 4 is first moved forwards and the needle 8 projects through the opening 6. Subsequently, the dispensing piston 18 is moved so as to expel the contents of the syringe 4. The device is designed to include a delatch mechanism. In particular, at the point at which the dispensing piston 18 reaches the end of the bore in the syringe 4, arms 22 at the end of the coupling 16 are
- 20 deflected by a collar 24 within the housing 2 so as to disengage from the drive element 12. The arms 22 and coupling 16 may then move within a central passage of the drive element 12. As a result, by virtue of the bias of spring 10, the coupling 16 moves inside the drive element 12, the syringe 4 is driven away from the opening 6 and the needle 8 is retracted within the opening 6.

25

Other similar delatch or retract arrangements have also been proposed. For instance, EP-A-0 516 473 discloses one embodiment in which, at the point at which the dispensing piston reaches the end of the bore in the syringe, a portion of the coupling instantaneously collapses in length as the retraction spring retracts the needle of the spring.

30

- In practice, all of these proposals suffer a problem that, owing to a stack up of tolerances of the various manufactured components of the assembled device (the dimensions of all manufacture components vary around a mean), it cannot be assured that the delatch mechanism will enable retraction of the syringe and needle at precisely the moment at
- 35 which the dispensing piston reaches the end of the bore. In practice, either the mechanism delatches before the dispensing piston reaches the end of the bore, such that the syringe is not emptied, or the piston reaches the end of the bore before the mechanism has moved sufficiently far to delatch.

Although this problem has been recognised before, for instance in US 6,159,181, the proposed solution has been to provide a user actuated retraction mechanism rather than an automatic one. This is considered to be undesirable.

5

UK patent applications nos. 0210123 and 0229384 describe a series of injection devices designed to deal with this problem. In each case, the device includes a housing that receives a syringe and includes a resilient member that biases the syringe from an extended position to a retracted position. An actuator is used to advance the syringe from its retracted position to its extended position and discharge the contents of the syringe. The actuator includes a drive element and a drive coupling that transfers movement of the drive element to the syringe. The drive coupling is compressible and compression of the drive element begins once a release mechanism has been triggered. Release of the syringe takes place a little time after the release mechanism is triggered, in an attempt to ensure that the syringe has been completely discharged. The compressible drive coupling may be elastically or inelastically compressible.

Satisfactory though these injector devices are, the use of a compressible drive coupling has this result. Once the release mechanism has been triggered, actuator has to do work against the compressible drive coupling. In the case of an elastically compressible drive coupling, the actuator must work to increase the elastic potential energy of the coupling. In the case of an elastically compressible drive coupling, the actuator must work against the forces that resist its compression, such as fluid viscous forces. In each case, therefore, a proportion of the force that the actuator is capable of applying is diverted from the syringe to the compressible coupling, which means that the force applied to the syringe suddenly drops when the release mechanism is triggered. This may have adverse consequences.

The injection devices according to the present invention represent an improvement over those described in UK patent application nos. 0210123 and 0229384.

30

An injection device according to a first embodiment of the present invention comprises:

a housing adapted to receive a syringe having a discharge nozzle, the housing including means for biasing the syringe from an extended position in which the discharge nozzle extends from the housing to a retracted position in which the discharge nozzle is contained within the housing;

an actuator for exerting on one or more components of the syringe one or more forces that advance the syringe from its retracted position to its extended position and discharge the contents of the syringe through its discharge nozzle; and

a release mechanism, activated when one or more of the said components of the syringe have been advanced to one or more nominal release positions, adapted to release the syringe from the action of the actuator, whereupon the biasing means restores the syringe to its retracted position, the release of the syringe being delayed after such  
5 activation to allow continued exertion of the discharging force at substantially its magnitude immediately prior to such activation, to discharge any contents of the syringe remaining before the syringe is released.

The predetermined period of delay can be used to compensate for any stacking of  
10 tolerances. It becomes possible to ensure that the syringe has expelled its entire contents before it is retracted. It is not necessary for various components to be constructed with critical tolerances to ensure that the syringe is retracted just at the point at which its contents are fully dispensed.

15 Triggering of the release mechanism can be designed to occur before the contents of the syringe are fully dispensed. The predetermined delay is so designed that for all variations within the intended tolerances of the components, actual release of the syringe will not occur until after its contents have been fully dispensed.

20 The improvement represented by the present invention as compared with UK patent application nos. 0210123 and 0229384 is that, following activation of the release mechanism, the discharging force continues to be exerted at substantially its magnitude immediately beforehand.

25 The actuator may consist of means for developing motion, and a coupling that is borne upon by the motion-developing means and in turn bears upon the said one or more components of the syringe, thus exerting the said one or more advancing and discharging forces. In that case, the continued exertion of the discharging force at the relevant magnitude can be assured by providing for the distance between the point at which the  
30 motion-developing means bears upon the coupling and the point at which the coupling bears upon the said one or more components of the syringe to be substantially invariable. In this context, the term "motion-developing means" is intended to mean that component of the actuator which first develops motion and to exclude any downstream components that transfer the motion of that component to other components of the device.

35

With this in mind, an injection device according to a second embodiment of the present invention comprises:

a housing adapted to receive a syringe having a discharge nozzle, the housing

including means for biasing the syringe from an extended position in which the discharge nozzle extends from the housing to a retracted position in which the discharge nozzle is contained within the housing;

- means for developing motion and a coupling that is borne upon by the motion-
- 5 developing means and in turn bears upon one or more components of the syringe to advance the syringe from its retracted position to its extended position and to discharge its contents through the discharge nozzle, in which the distance between the point at which the motion-developing means bears upon the coupling and the point at which the coupling bears upon the said one or more components of the syringe is substantially invariable; and
- 10 a release mechanism, activated when one or more of the said components of the syringe have been advanced to one or more nominal release positions, to release the syringe from the coupling, whereupon the biasing means restores the syringe to its retracted position, the release of the syringe being delayed after such activation to allow any contents of the syringe remaining to be discharged by the coupling before the syringe
- 15 is released.

- Invariance of the distance between the point at which the motion-developing means bears upon the coupling and the point at which the coupling bears upon the said one or more components of the syringe is most conveniently provided by a substantially incompressible
- 20 coupling.

Both the motion-developing means and the biasing means may comprise a resilient member.

- 25 Preferably, the release mechanism is activated by the coupling reaching a predetermined position relative to the housing. In this way, the syringe can be secured within the housing at a position to ensure that the mechanism is triggered before its contents are fully dispensed.
- 30 Thus, the coupling advances and, at a predetermined position along the housing, the mechanism is triggered. This may be achieved by a feature of the coupling interacting with a trigger located on the inside of the housing.

- Preferably, the release mechanism includes a resiliently biased release member for
- 35 releasing the syringe, a trigger member for holding the release member and means for damping movement of the release member wherein, when the mechanism is activated, the trigger member releases the release member and the release member moves, under the influence of its resilient bias and against the resistance of the damping means, to release

the syringe.

In this way, although the release member is biased to move to a position for releasing the syringe, the trigger member holds the release member back. Once the mechanism is triggered and the trigger member releases the release member, the release member still has to travel to the required position for releasing the syringe. By providing means for damping movement of the release member, movement of the release member is delayed such that the release of the syringe is also delayed.

- 10 Preferably, the damping means includes a fluid for damping the movement of the release member.

The damper could be provided on one or other of the release member and the housing with a pocket of fluid held in the other of the release member and housing.

- 15 Preferably, the coupling comprises first and second elements and the release mechanism is adapted to disengage the first and second coupling elements to release the syringe.

- Once the first and second coupling elements are disengaged, one can move relative to the other. In particular, the second coupling element may be allowed to retract with the syringe.

- Preferably, the first coupling element comprises an annular wall defining a central bore and the second coupling element includes resilient arms that engage the annular wall and are capable of inward deflection to disengage from the annular wall and allow the second coupling element to move relative to the first coupling element within the bore.

This provides a convenient and advantageous arrangement by which the first and second coupling elements can move relative to each other.

- 30 Inward deflection of the resilient arms may be achieved by means of a collar that is moveable within the housing. Movement of the collar allows it to be released from a first position upon activation of the release mechanism and move to a second position, in which the first and second coupling elements are disengaged.

- 35 Preferably, the damping means are provided between the collar and the housing. In this way, movement of the collar can be delayed to provide the required delay for release of the syringe.

Preferably, the trigger member is moveable by the coupling from a position to impede movement of the release member and a position to allow movement of the release member. Hence, the trigger member may take the form of a latch which physically impedes  
5 movement of the release member, for instance the collar. The first or second coupling element then physically moves the latch to enable the release member, to move and then subsequently release the syringe.

An alternative release mechanism includes an inertial mass moveable with the coupling  
10 and a release member actuated by the inertial mass to release the syringe, such that when the coupling reaches the said predetermined position relative to the housing, the inertial mass continues to move irrespective of movement of the coupling, so as to actuate the release member to release the syringe.

15 In this way, release of the syringe is not dependent on the relative positions of a number of different components and, hence, is not affected by tolerance stacking. Relative movement of the inertial mass and, hence, release of the syringe can occur as a direct result of the contents of the syringe being fully dispensed. It will be appreciated that the inertial mass has a momentum as it moves with the coupling towards the end of the housing. Once the  
20 contents of the syringe are fully dispensed, the coupling stops moving. The momentum of the inertial mass causes it to continue moving, and this movement can be used to actuate the release member to release the syringe.

Preferably, the inertial mass is mounted on the coupling so as to allow relative movement  
25 of the inertial mass in the direction of movement of the coupling during discharge of the syringe.

Preferably, the inertial mass is mounted on the coupling by means of a thread. In this way, rather than have the inertial mass move only with an axial or longitudinal movement  
30 relative to the coupling, the inertial mass can be caused additionally to spin or rotate. This allows a more controlled and steady momentum to be set up in the inertial mass and then used subsequently to release the syringe.

Preferably, the injection device further includes a stop that engages the inertial mass to  
35 prevent relative movement of the inertial mass in the direction opposite to the direction of movement of the coupling during discharge of the syringe. Preferably, the stop is provided on the coupling.

This is a convenient way of ensuring maximum transfer of momentum.

Preferably, the coupling comprises first and second elements and the release member is moveable by the inertial mass to disengage the first and second coupling elements to  
5 release the syringe.

The first coupling element may engage with the second in any convenient manner. For instance, one of them may include an annular wall defining a central bore and the other may include resilient arms that engage the annular wall and are capable of inward  
10 deflection to disengage from the annular wall and allow the two coupling elements to move relative to each other. According to the type of engagement chosen, the release member may take any suitable form. For instance, for the example described here, the release member could include a moveable collar acting on the arms to deflect them inwardly.

15 the release member is integral with the inertial mass and connects the first and second coupling elements, such that relative movement of the inertial mass and the coupling separates the first and second coupling elements to release the syringe.

The release member may be integral with the inertial mass and connect the two coupling  
20 elements, such that relative movement of the inertial mass and the coupling separates the two coupling elements to release the syringe.

In other words, the inertial mass may itself form part of a component which joins one coupling element to the other. Once the syringe has been fully discharged and the inertial  
25 mass moves relative to the coupling, it can be arranged to release the connection between the two coupling elements, allowing retraction of the syringe.

Preferably, the two coupling elements are provided with coaxial threads and the release member is provided with a corresponding thread to connect the coupling elements.

30

In this way, when the syringe is fully discharged, the momentum of the inertial mass will cause it to rotate on its thread relative to the coupling, thereby releasing the connection between the two coupling elements and allowing retraction of the syringe.

35 Alternatively, the release member may be moveable to disengage the motion-developing means from the coupling. This may be achieved in the same manner as described above for the two coupling elements.



Where the release member is not an integral member of the inertial mass, it may be provided on an inner part of the housing.

The invention will be more clearly understood from the following description given by way of example only, with reference to the accompanying drawings in which:

Figure 1 illustrates a known construction for an injection device;

Figures 2 to 7 illustrate a first embodiment of the present invention at different stages of its operation;

Figures 8 to 10 illustrate a second embodiment of the present invention at different stages of its operation; and

Figure 11 illustrates a variation on the second embodiment.

The present invention can be embodied in any suitable outer housing such as illustrated in Figure 1, in particular having an opening 6 in its end through which the needle 8 of a syringe 4 may extend and a release mechanism 20 at its opposite end for releasing a spring 14 for deploying and emptying the contained syringe.

Figure 2 illustrates schematically the key components of a preferred embodiment for use in a preferred housing.

A drive spring 30 engages with a first coupling element 32, itself providing drive to a second coupling element 34. Thus, the drive spring 30 here acts as the motion-developing means for the injection device. Alternative motion-developing means could be used, for example a pneumatic piston operated by a compressed gas canister or the actuator of a solenoid in an electrically powered device. The second coupling element 34 is provided to engage the dispensing piston 18 of a syringe 4 in the device. Thus, when the coupling elements 32, 34 are released by an appropriate release mechanism, the drive spring 30 drives the first coupling element 32 and, hence, the second coupling element 34 towards an end 36 of the housing. As is known, when the second coupling element 34 first pushes upon the dispensing piston 18 of the syringe 4, it will move the syringe 4 itself towards the end 36 of the housing as illustrated in Figure 3. Indeed, the syringe 4 will be moved such that its needle 8 protrudes from the end 36 of the housing so as to penetrate the skin of a user.

As illustrated in Figure 4, further movement of the first coupling element 32 and second coupling element 34 will cause the dispensing piston 18 to move relative to the cylindrical housing of the syringe 4 and thereby expel the contents of the syringe 4 through the needle 8.

The injection device also includes a mechanism for retracting the syringe 4. Although not illustrated, a spring may be provided to bias the syringe 4 inwardly of the housing and away from the end 36. Once the dispensing piston 18 has reached the end of its travel in the syringe 4, the mechanism may release the syringe such that the spring moves the syringe 4 inwardly of the housing, thereby retracting the needle 8 from the user.

According to the illustrated embodiment, the mechanism includes a release member in the form of a collar 38. The collar 38 is moveable axially within the housing and is biased away from the end 36 of the housing by means of a spring 40. In this embodiment, collar 38 is designed to interact with resilient arms 42 provided on an end of the second coupling element 34 engaging the first coupling element 32. The resilient arms 42 interconnect the first coupling element 32 and second coupling element 34 such that the first coupling element 32 may push against and transfer movement to the second coupling element 34.

As illustrated in Figure 5, the collar 38 is able to push upon the resilient arms 42 and deflect them inwardly. In this way, as illustrated in Figure 6, the resilient arms 42 are pushed inwardly into a through hole defined within the first coupling element 32. The syringe 4 is thereby released and can travel as illustrated in Figure 7 so as to retract the needle 8.

According to the present invention, the syringe is not released until a predetermined period after the mechanism is triggered. In this respect, it will be seen in the Figures that at least one trigger member 44 is provided so as to prevent the collar 38 moving by virtue of the spring 40. Hence, in Figures 2 and 3, the collar 38 is held in a position towards the end 36 of the housing. The trigger member(s) 44 are provided adjacent corresponding recesses 46 into which they may be deflected.

As the first coupling element 32 and second coupling element 34 move towards the end 36 of the housing, at some predetermined position, they deflect the trigger member(s) 44 so as to trigger the mechanism. As illustrated, the trigger member(s) 44 is provided at the outer periphery of the path of the first coupling element 32. Hence, for this embodiment, the first coupling element 32 itself deflects the trigger member(s) outwardly. However, it should be appreciated that other similar trigger members could be provided which are deflected either by the first coupling element 32 or the second coupling element 34.

As illustrated in Figure 4, with the trigger member(s) deflected into the corresponding recess(es) 46, the collar 38 is free to move away from the end 36 of the housing under the

power of spring 40 so as to deflect the resilient arms 42 and release the syringe 4 as described above.

It will be appreciated that there will be a predetermined time interval between deflection of the trigger member(s) 44 and deflection of the resilient arms 42 due to the time taken for the collar 38 to move. During this predetermined time interval, the first coupling element 32 and second coupling element 34 will continue to move the dispensing piston 18 towards the end surface of the syringe 4. Indeed, in the preferred embodiment, the components are designed such that the trigger member(s) 44 are deflected and the mechanism is triggered before the dispensing piston 18 reaches the end surface of the syringe 4 (see Figure 4), but that the syringe 4 is not released until after the dispensing piston 18 reaches the end surface of the syringe 4. In this embodiment, this is when the resilient arms 42 are deflected (see Figures 5 and 6). It will be noted that, throughout the period of time taken by the collar 38 to collapse the resilient arms 42, the first coupling element 32 continues to bear directly upon the resilient arms 42 of the second coupling element 34. Thus, substantially all of the resilient force of the drive spring 30 is transferred, via the first and second coupling elements 32, 34, to the dispensing piston of the syringe. Substantially no work is done by the drive spring 30 on the collar 38, because the point contacts of the collar 38 on the resilient arms 42 are substantially frictionless.

Although it is possible to rely on frictional forces to resist movement of the collar 38 and thereby introduce the desired delay, in the preferred embodiment, a damping arrangement is provided.

As illustrated in Figures 2 to 7, the housing is provided with a damping pocket 48 within which a damper 50 on the outer periphery of the collar 38 may move. In this respect, it should be appreciated that the arrangement of pocket and damper between the housing and collar can be reversed.

The pocket 48 may be filled with a damping fluid, such as a liquid, or may rely merely on movement of a gas, such as air. Once the collar 38 is released by the trigger member(s) 44, the damping arrangement, 48, 50 resists movement and thereby provides an increased delay before the syringe 4 is released. As explained above, this can be used to ensure that the dispensing piston 18 has fully expelled the contents of the syringe 4 before the syringe 4 is released.

While a particular embodiment has been described, it should be appreciated that a large number of variations may be introduced. It is not necessary for the release member to be a

collar or, indeed, the collar 38 might rotate instead of or as well as move axially. Furthermore, any other form of damping suitable for the release member may be used and, as mentioned above, different forms of trigger member are also possible.

- 5 Figures 8, 9 and 10 illustrate schematically key components of an alternative embodiment. Once again, these components can be embodied in an overall housing such as illustrated in Figure 1 with an equivalent release mechanism. Also, many of the features described with reference to Figures 2 to 7 could also be used with this embodiment to disconnect the drive spring from the first coupling element, or the first coupling element from the second  
10 coupling element so as to enable retraction of the syringe under the power of a retraction spring.

As with previous arrangements, a first coupling element 70 engages with a second coupling element 72 which in turn engages with the dispensing piston 18 of a syringe 4. A  
15 drive spring 74 may be provided to move the syringe 4 towards an end of the housing so as to extend the needle 8 of the syringe 4 and subsequently to move the dispensing piston 18 within the syringe 4 so as to expel the contents of the syringe 4. Alternatively, other motion-developing means may be used.

- 20 Although not illustrated, a resilient member such as a spring may also be provided to bias the syringe and needle inwardly of the housing such that, at an appropriate time, the syringe 4 and needle 8 may be retracted back into the housing.

A mechanism is provided whereby the syringe 4 is released at an appropriate time so that  
25 the resilient member can retract the syringe 4. Details of the components which hold the syringe and release it are not essential to the invention. Components such as described above and other known mechanisms may be used. However, the present invention proposes a novel and inventive arrangement for triggering retraction of the syringe 4.

- 30 In the embodiment illustrated in Figures 8 to 10, an inertial mass 76 is mounted on the second coupling element 72.

When the first coupling element 70 and second coupling element 72 move forwards so as to move the dispensing piston 18 and expel the contents of the syringe 4, the inertial mass  
35 76 moves with them. However, when the dispensing piston 18 reaches the internal end surface of the syringe 4 as illustrated in Figure 8, the first coupling element 70 and second coupling element 72 stop moving relatively abruptly. Due to the momentum of the inertial mass 76, the inertial mass 76 continues to move forwards.

As illustrated, a trigger 78 is provided in the device for actuating the retraction mechanism. In particular, the inertial mass 76 will move from its original position on the second coupling element 72 to a position where it will operate the trigger 78 and thereby actuate the retraction mechanism. It will be noted that, throughout the period of time taken by the inertial mass 76 to reach the trigger 78, the first coupling element 70 continues to bear directly upon the second coupling element 72. Thus, substantially all of the resilient force of the drive spring 74 is transferred, via the first and second coupling elements 70, 72, to the dispensing piston of the syringe.

10

It will be appreciated that a substantial number of variations are possible. The inertial mass could be mounted on the first coupling element 70 or, indeed, it could be mounted on a separate component which also moves with the dispensing piston 18. The important point is of course that the inertial mass should move to actuate the retraction mechanism in response to the dispensing piston 18 stopping.

15

Similarly, the trigger 78 can take any appropriate form and can be mounted anywhere within the housing, for instance on the housing wall or on the second coupling element 72. The nature of the trigger 78 may vary according to the particular retraction mechanism used.

20

In the illustrated embodiment, a stop 80 is provided behind the inertial mass 76. The stop 80 functions to push the inertial mass 78 forwards when the first coupling element 70 and second coupling element 72 first start moving forwards so as to move the syringe 4 and dispensing piston 18. It will be appreciated that, at this point in the operation of the device, there will be a tendency for the inertial mass 76 to move backwards away from the dispensing piston 18 due to its inertia. By providing the stop 80, the inertial mass 76 is positively driven forwards with the second coupling element 72 such that the energy and momentum provided to the inertial mass 76 is maximised. This similarly maximises its ability to operate the trigger 78.

25

The stop 80 may be a separate component or be formed as an integral part of the mounting for the inertial mass. For instance, where the inertial mass is able to move relative to the second coupling element along a channel, the channel might only start at a predetermined position along the length of the second coupling element 72 such that the end wall of the channel forms the stop.

30

In the preferred embodiment, the inertial mass 76 is mounted rotatably by means of a

thread. In the illustrated embodiment, the inertial mass 76 may have a female thread engaging with a corresponding male thread around the second coupling element 72. However, as mentioned above, the inertial mass 76 could alternatively be mounted on other components.

5

In this way, when the dispensing piston 18 reaches the end of its travel and the inertial mass 76 starts to move relative to the second coupling element 72, the inertial mass will rotate or spin as well as move forwards towards the dispensing piston 18. This rotation provides a rotational inertia or momentum which is more controlled and sustains over a longer period of time. In particular, it can be more effective in providing assured actuation of any trigger.

In alternative embodiments, the inertial mass and release member may be integrated so as to themselves form the retraction mechanism. In particular, the release member may take the form of a thread which joins the first coupling element to the second coupling element.

15

An embodiment is illustrated in Figure 11.

When the dispensing piston 18 reaches the end of its travel and stops, the inertial mass 108 continues to move and hence rotates about the first coupling element 102 and second coupling element 104 such that its thread forming the release member unscrews from the threads joining the first coupling element 102 and the second coupling element 104. Once the thread has fully unscrewed then second coupling element 104 is able to move relative to the first coupling element 102 and the syringe 4 is retracted by means of the resilient member 106. Throughout the period of time taken by the inertial mass 108 to unscrew from the threads on the second coupling element 104, the first coupling element 102 continues to bear upon the second coupling element 104 via the inertial mass 108. Thus, substantially all of the drive force transferred to the dispensing piston of the syringe.

20

25

Similar alternative arrangements are also possible.

30

New Claims

1. An injection device comprising:
  - a housing adapted to receive a syringe having a discharge nozzle, the housing
  - 5 including means for biasing the syringe from an extended position in which the discharge nozzle extends from the housing to a retracted position in which the discharge nozzle is contained within the housing;
  - an actuator for exerting on one or more components of the syringe one or more forces that advance the syringe from its retracted position to its extended position and
  - 10 discharge the contents of the syringe through its discharge nozzle; and
  - a release mechanism, activated when one or more of the said components of the syringe have been advanced to one or more nominal release positions, adapted to release the syringe from the action of the actuator, whereupon the biasing means restores the syringe to its retracted position, the release of the syringe being delayed after such
  - 15 activation to allow continued exertion of the discharging force at substantially its magnitude immediately prior to such activation, to discharge any contents of the syringe remaining before the syringe is released.
2. An injection device according to claim 1 in which the actuator comprises means for
- 20 developing motion and a coupling that is borne upon by the motion-developing means and in turn bears upon the said one or more components of the syringe, thus exerting the said one or more advancing and discharging forces.
3. An injection device according to claim 2 in which the distance between the point at
- 25 which the motion-developing means bears upon the coupling and the point at which the coupling bears upon the said one or more components of the syringe is substantially invariable.
4. An injection device comprising:
  - a housing adapted to receive a syringe having a discharge nozzle, the housing
  - 30 including means for biasing the syringe from an extended position in which the discharge nozzle extends from the housing to a retracted position in which the discharge nozzle is contained within the housing;
  - means for developing motion and a coupling that is borne upon by the motion-
  - 35 developing means and in turn bears upon one or more components of the syringe to advance the syringe from its retracted position to its extended position and to discharge its contents through the discharge nozzle, in which the distance between the point at which the motion-developing means bears upon the coupling and the point at which the coupling

bears upon the said one or more components of the syringe is substantially invariable; and  
a release mechanism, activated when one or more of the said components of the  
syringe have been advanced to one or more nominal release positions, to release the  
syringe from the coupling, whereupon the biasing means restores the syringe to its  
5 retracted position, the release of the syringe being delayed after such activation to allow  
any contents of the syringe remaining to be discharged by the coupling before the syringe  
is released.

5. An injection device according to claim 3 or claim 4 in which the coupling is  
10 substantially incompressible.

6. An injection device according to any one of claims 2-5 in which the motion-  
developing means is a resilient element.

15 7. An injection device according to any preceding claim in which the biasing means  
comprises a resilient member.

8. An injection device according to any preceding claim in which the release  
mechanism is activated by the coupling reaching a predetermined position relative to the  
20 housing.

9. An injection device according to claim 8 in which the release mechanism includes:  
a resiliently biased release member for releasing the syringe;  
a trigger member for holding the release member; and  
25 means for damping movement of the release member;  
in which, when the mechanism is activated, the trigger member releases the release  
member and the release member moves, under the influence of its resilient bias and against  
the resistance of the damping means, to release the syringe.

30 10. An injection device according to claim 9 in which the damping means includes a  
fluid for damping the movement of the release member.

11. An injection device according to claim 10 in which the damping fluid is a liquid.

35 12. An injection device according to any one of claims 9-11 in which the release  
member includes a collar.

13. An injection device according to claim 12 in which the damping means is provided



between the collar and the housing.

14. An injection device according to any one of claims 9-13 in which the trigger member is moveable by the coupling from a position that impedes movement of the release member to a position that allows movement of the release member.

15. An injection device according to any preceding claim in which the coupling comprises first and second elements and the release mechanism is adapted to disengage the first and second elements to release the syringe.

10

16. An injection device according to claim 15 in which the first element comprises an annular wall defining a central bore and the second element includes resilient arms that engage the annular wall and are capable of inward deflection to disengage from the annular wall and allow the second element to move relative to the first element within the bore.

15

17. An injection device according to claim 8, in which:

the release mechanism includes an inertial mass moveable with the coupling and a release member actuated by the inertial mass to release the syringe, such that when the coupling reaches the said predetermined position relative to the housing, the inertial mass continues to move irrespective of movement of the coupling, so as to actuate the release member to release the syringe.

18. An injection device according to claim 17 in which the inertial mass is mounted on the coupling so as to allow relative movement of the inertial mass in the direction of movement of the coupling during discharge of the syringe.

19. An injection device according to claim 18 in which the inertial mass is mounted on the coupling by means of a thread.

20. An injection device according to claims 18 or claim 19, further including a stop that engages the inertial mass to prevent relative movement of the inertial mass in the direction opposite to the direction of movement of the coupling during discharge of the syringe.

21. An injection device according to claim 20 in which the stop is provided on the coupling.

22. An injection device according to any one of claims 17 to 21 in which the coupling comprises first and second elements and the release member is moveable by the inertial

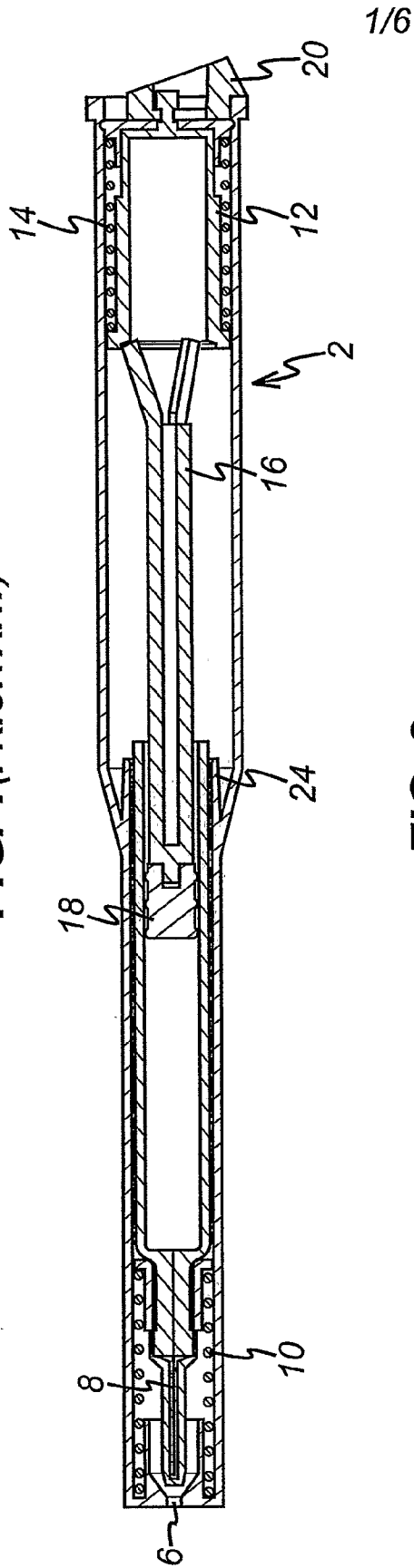
mass to disengage the first and second elements to release the syringe.

23. An injection device according to claim 22 in which the release member is integral with the inertial mass and connects the first and second elements, such that relative  
5 movement of the inertial mass and the coupling separates the first and second elements to release the syringe.

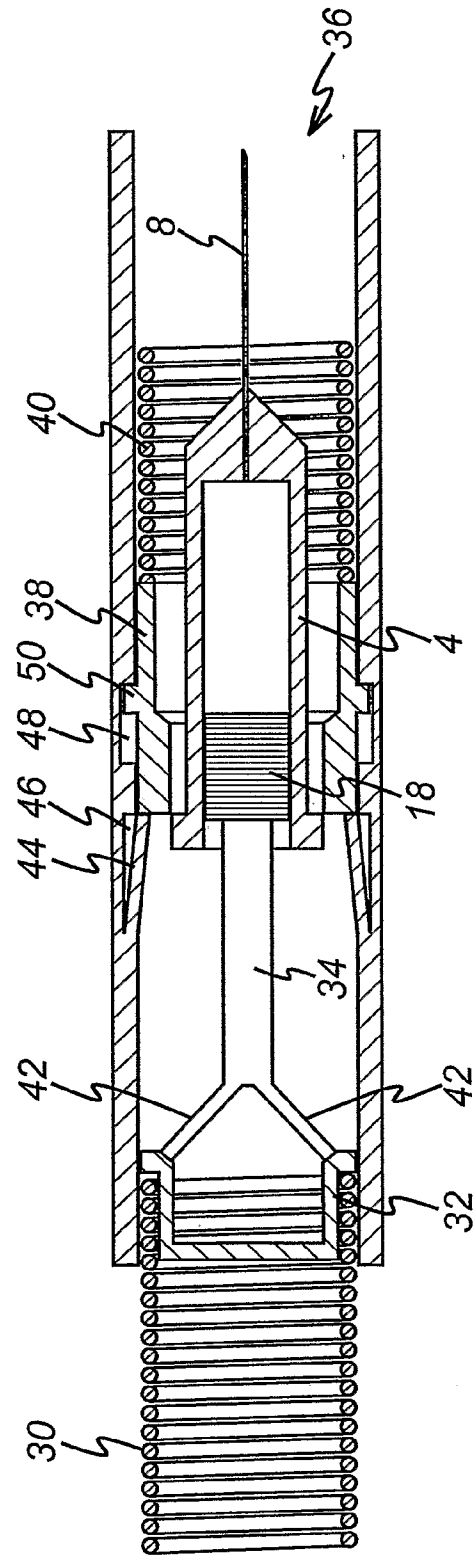
24. An injection device according to claim 23 in which the first and second elements are provided with coaxial threads and the release member is provided with a corresponding  
10 thread to connect the first and second coupling elements.

25. An injection device substantially as described herein with reference to and/or substantially as illustrated in figs. 2-7 or figs. 8-10 of fig. 11 of the accompanying drawings.

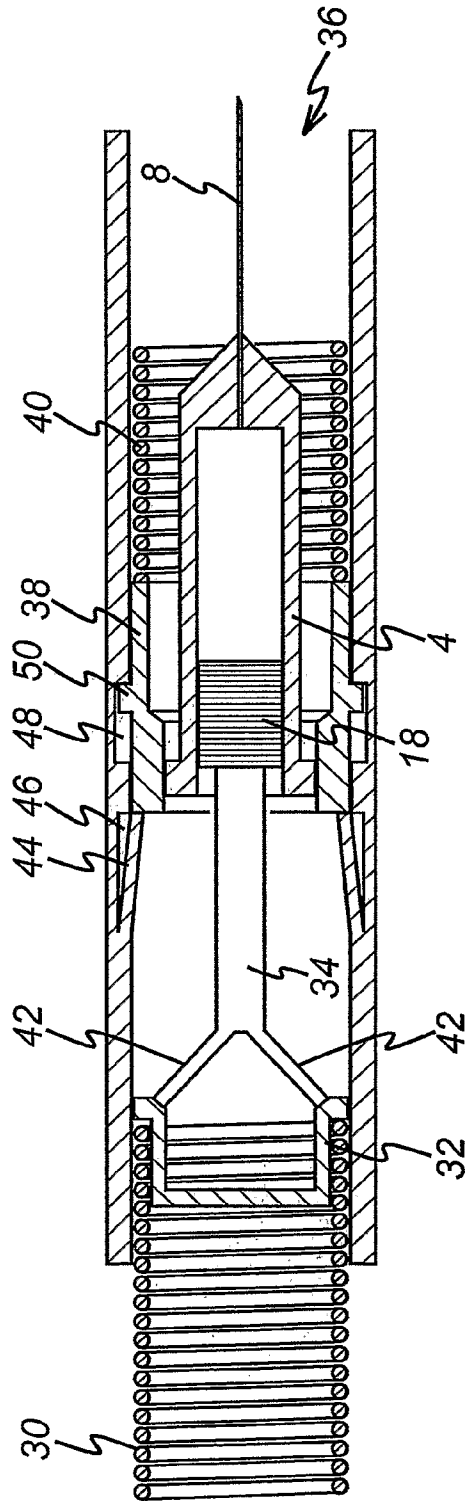
**FIG. 1 (PRIOR ART)**



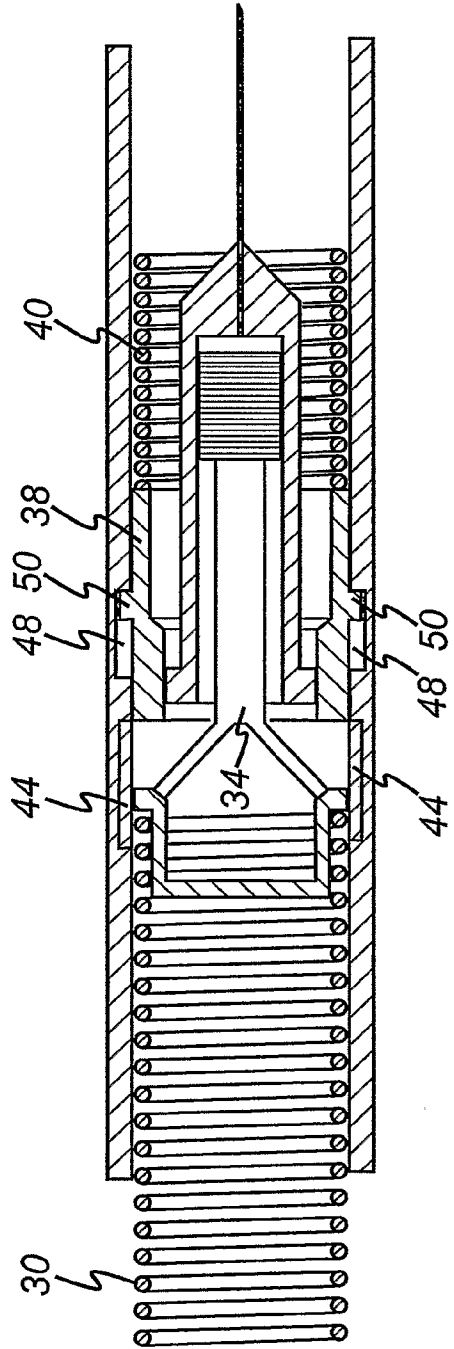
**FIG. 2**



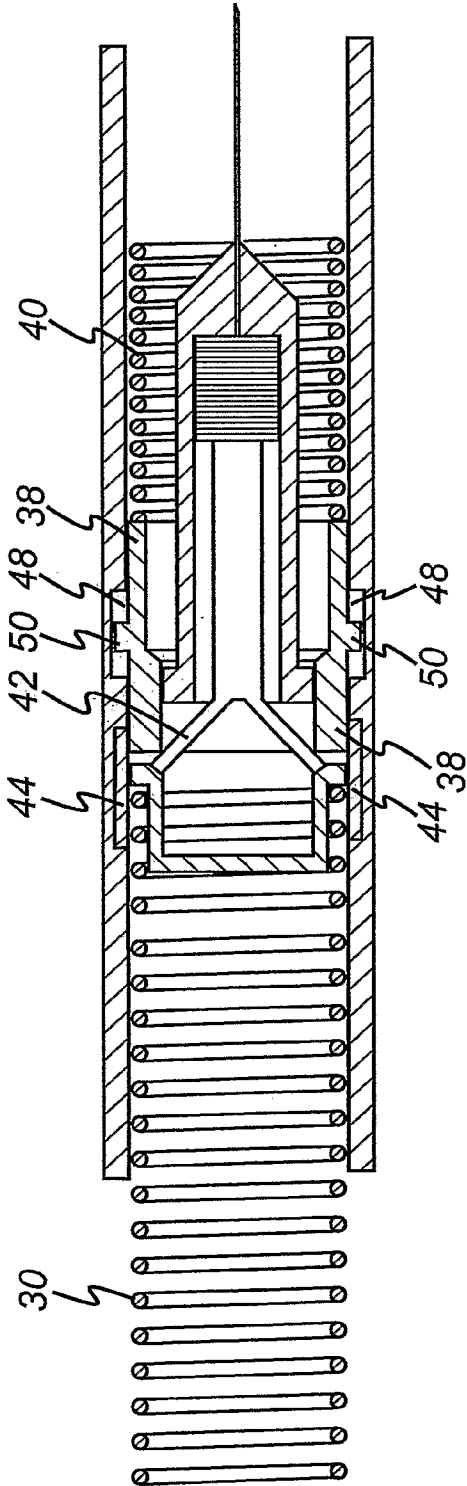
**FIG. 3**



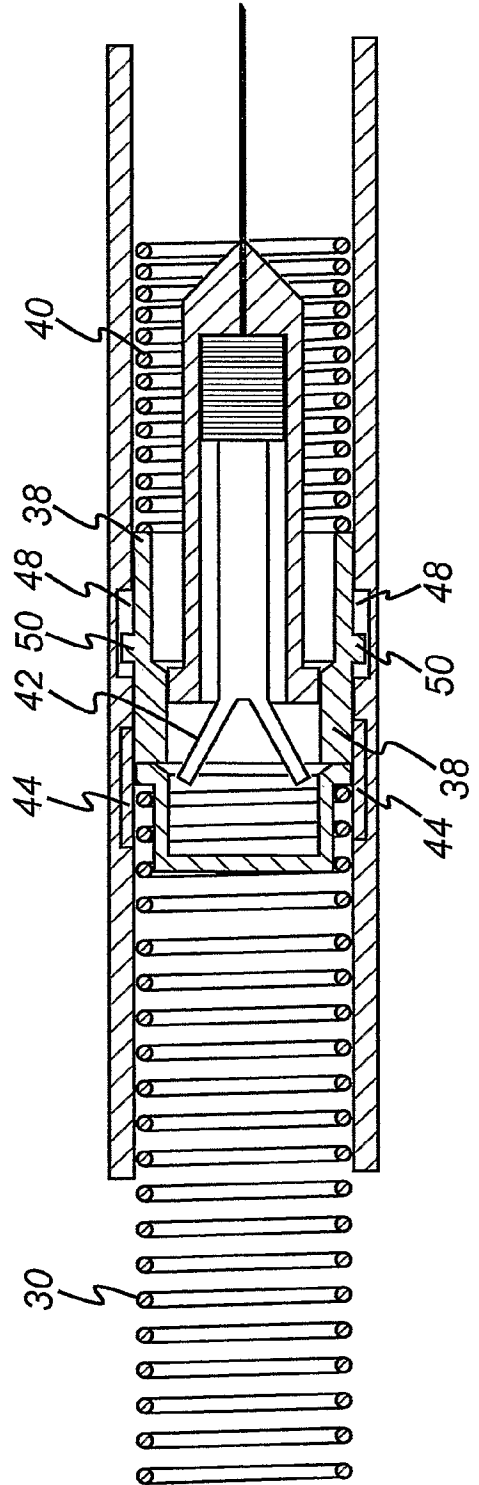
**FIG. 4**



**FIG. 5**

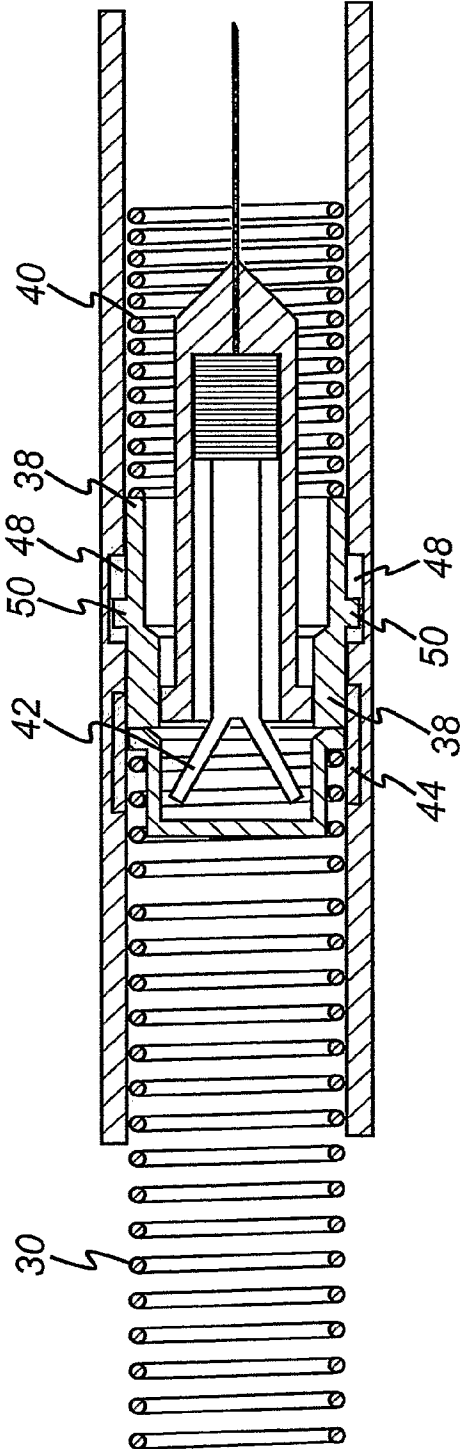


**FIG. 6**

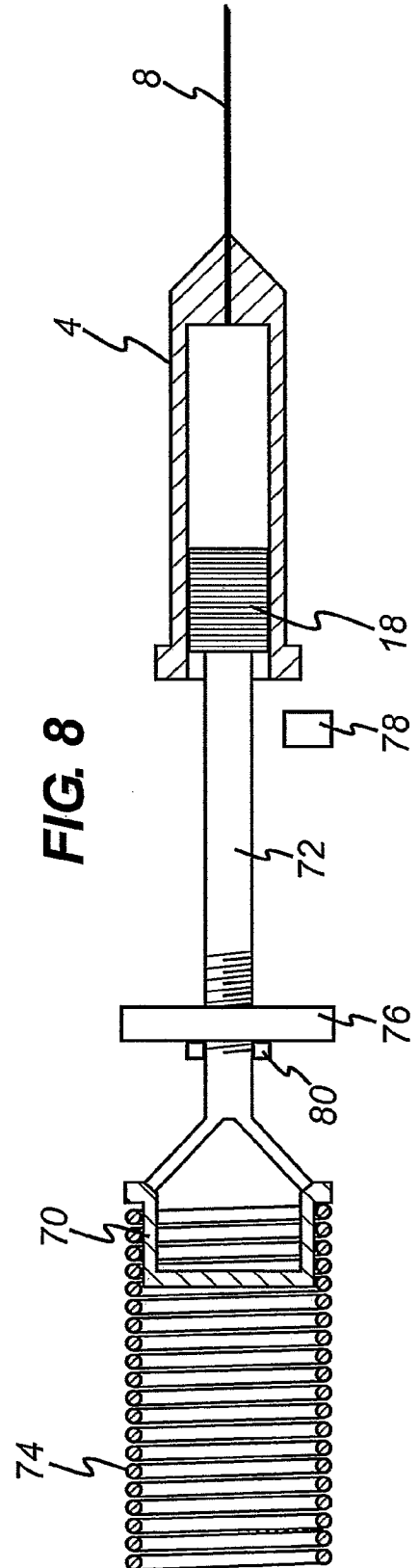


4/6

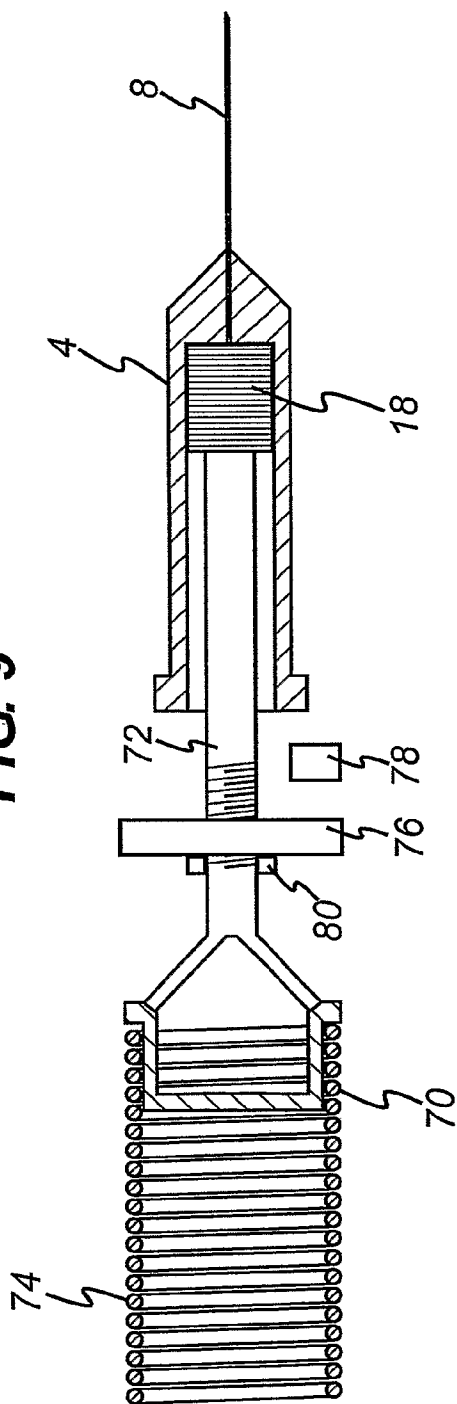
**FIG. 7**



**FIG. 8**



**FIG. 9**



**FIG. 10**

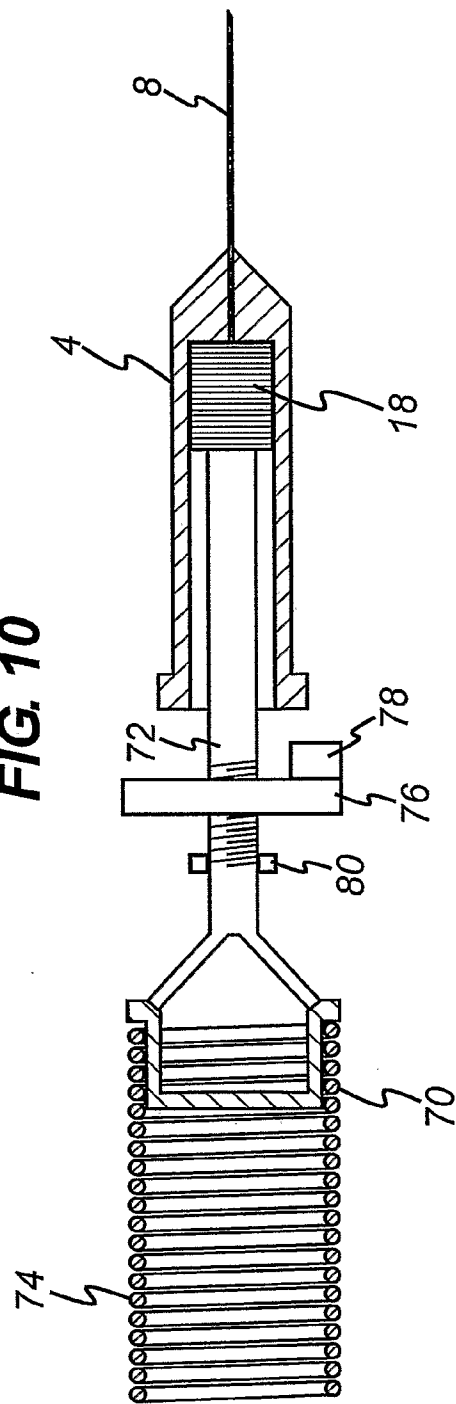
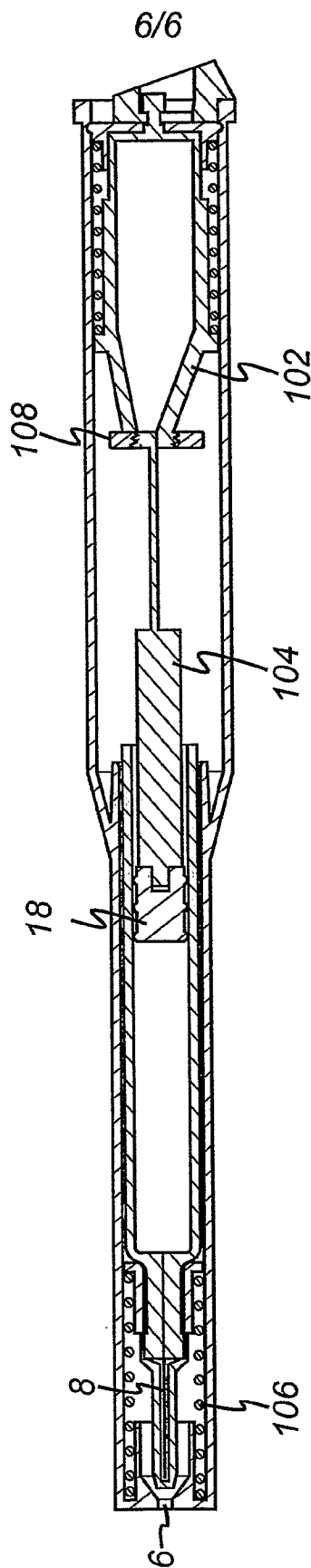


FIG. 11





(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
1 July 2004 (01.07.2004)

PCT

(10) International Publication Number  
**WO 2004/054645 A3**

(51) International Patent Classification<sup>7</sup>: A61M 5/32, 5/20

(74) Agents: TUNSTALL, Christopher, Stephen et al.; Carpmals & Ransford, 43-45 Bloomsbury Square, London WC1A 2RA (GB).

(21) International Application Number:  
PCT/GB2003/005494

(22) International Filing Date:  
17 December 2003 (17.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
0229404.9 17 December 2002 (17.12.2002) GB  
0325596.5 3 November 2003 (03.11.2003) GB

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): CILAG AG INTERNATIONAL [CH/CI]; Landis & Gyrstrasse 1, CH-6300 Zug (CH).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): HARRISON, Nigel, David [GB/GB]; 15 Barley Way, Linton, Cambridge CB1 6YN (GB). BRADY, Matthew, James [GB/GB]; 6 Wattle Close, Cambourne, Cambridgeshire CB3 6BU (GB). BERMAN, Gregory [GB/GB]; 45 Highfield Avenue, Cambridge CB4 2AJ (GB). JOHNSTON, David, Maxwell [GB/US]; 12134 East Run Drive, Lawrenceville, NJ 08648 (US). HABESHAW, Rosemary, Louise [GB/GB]; 84A Blinco Grove, Cambridge CB1 7TS (GB).

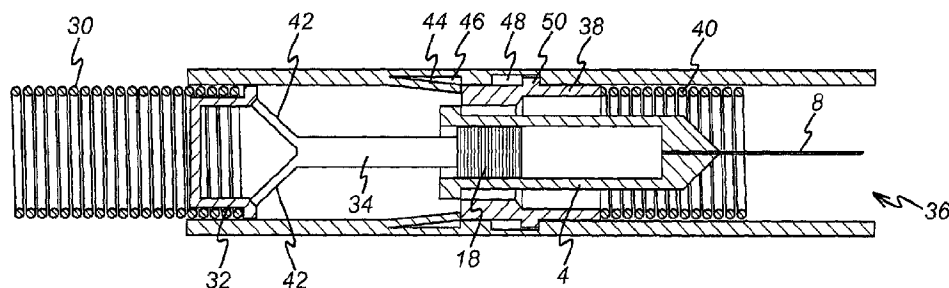
**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:  
16 September 2004

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: INJECTION DEVICE



(57) Abstract: An injection device including a housing for containing a syringe (4) having a dispensing piston (18) to expel the contents of the syringe through the needle (8), a resilient member for biasing (40) the syringe and the needle inwardly off the housing, a first coupling element (32) moveable towards said one end so as to move the needle of the syringe out of the opening and to move the dispensing piston of the syringe towards the end of the surface, a mechanism operable to release the syringe such that the needle moves inwardly off the housing, a drive coupling for extending from said first coupling element to the dispensing piston of the syringe so as to transfer movement of said first coupling element to the dispensing piston wherein the mechanism is triggered to release the syringe and includes components to delay release of the syringe until a predetermined period after being triggered such that it can be ensured that the dispensing piston reaches the end surface before the syringe is released.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 03/05494

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/32 A61M5/20

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 03/092771 A (PA KNOWLEDGE LTD; MARTIN JEFFREY ; HUGHES MARTIN LAWRENCE (GB)) 13 November 2003 (2003-11-13) cited in the application page 12, line 21 - page 17, line 7; figures 1-9	1-12, 14, 25
X,P	GB 2 388 033 A (PA CONSULTING SERVICES) 5 November 2003 (2003-11-05) cited in the application claim 1; figures 1-9 page 12, line 14 - page 16, line 29 ----- -/--	1-12, 14, 25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

23 March 2004

Date of mailing of the international search report

09.07.2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Reinbold, S

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 03/05494

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/29720 A (PA CONSULTING SERVICES ;REVELL WILLIAM JAMES (GB)) 9 November 1995 (1995-11-09)	1-5, 7-11,25
Y	page 10, paragraph 5 - page 11, paragraph 5; figures 1-4 page 13, paragraph 2 - page 13, paragraph 4	13,15,16
X	----- US 6 099 504 A (GROSS JOSEPH ET AL) 8 August 2000 (2000-08-08) column 7, line 7 - line 57; figures 1-11 -----	1
X	WO 95/35126 A (JEFFREY PETER ;SAFE T LTD (GB)) 28 December 1995 (1995-12-28)	1
Y	page 14, paragraph 3 - page 15, paragraph 1; figures 1-12	13,15,16
A	----- US 6 270 479 B1 (AAMARK MIKAEL ET AL) 7 August 2001 (2001-08-07) column 12, line 58 - column 13, line 35; figure 1 -----	1-16,25

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 03/05494

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1-16, 25

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16,25

An injection device comprising a release mechanism, as described in claim 8 in combination with independent claim 1 or 4, wherein said release mechanism comprises a damping means with fluid.

---

2. claims: 17-24

An injection device comprising a release mechanism, as described in claim 8 in combination with independent claim 1 or 4, wherein said release mechanism comprises an inertial mass.

---

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 03/05494

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03092771	A	13-11-2003	GB 2388033 A	05-11-2003
			GB 2396298 A	23-06-2004
			WO 03092771 A1	13-11-2003
GB 2388033	A	05-11-2003	WO 03092771 A1	13-11-2003
WO 9529720	A	09-11-1995	AU 2313495 A	29-11-1995
			WO 9529720 A1	09-11-1995
US 6099504	A	08-08-2000	IE 970782 A1	05-05-1999
			AU 9557298 A	24-05-1999
			CA 2308217 A1	14-05-1999
			EP 1024845 A1	09-08-2000
			WO 9922790 A1	14-05-1999
			JP 2001521792 T	13-11-2001
			ZA 9809580 A	28-04-1999
			AT 246013 T	15-08-2003
			DE 69816849 D1	04-09-2003
			DE 69816849 T2	26-02-2004
WO 9535126	A	28-12-1995	AU 709098 B2	19-08-1999
			AU 2680995 A	15-01-1996
			CA 2193231 A1	28-12-1995
			EP 0956061 A1	17-11-1999
			WO 9535126 A1	28-12-1995
			JP 10507935 T	04-08-1998
			US 5957897 A	28-09-1999
US 6270479	B1	07-08-2001	US 2001005781 A1	28-06-2001
			AU 1589300 A	15-05-2000
			EP 1124601 A1	22-08-2001
			JP 2002528182 T	03-09-2002
			WO 0024441 A1	04-05-2000
			TW 445156 B	11-07-2001